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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,507	02/05/2004	Taejoon Kwon	YPL0080US	6812

23413 7590 08/14/2009
CANTOR COLBURN, LLP
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EXAMINER

ZHOU, SHUBO

ART UNIT	PAPER NUMBER
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1631

NOTIFICATION DATE	DELIVERY MODE
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08/14/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/773,507	Applicant(s) KWON, TAEJOON	
	Examiner SHUBO (Joe) ZHOU	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7,9-12 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,9-12 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Finality

The finality of the last Office action mailed on 12/12/08 is withdrawn in view of the new ground of rejection below.

Amendment/Status of the Claims

The amendment filed 2/11/09 has been entered and based upon in the present Office action.

Claims 3, 8, and 13-14 are canceled.

Claims 1-2, 4-7, 9-12, and 15 are currently pending and under consideration.

Claim Rejections-35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2, 4-7, 9-12, and 15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Note that this new ground of rejection is applied in view of court decisions including the recent *In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Fed. Cir. 2008).

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Claims 1-2, 4-7, 9-12, and 15 are drawn to a method of determining a location of a target sequence in a genome sequence, the method comprising: inputting a target sequence; searching for identifier information and sequence information corresponding to the target sequence in a crosslink map, wherein the crosslink map comprises records of sequence information for a plurality of versions of a genome sequence; determining a reference group comprising a reference sequence information for an organism, wherein the reference sequence information is represented in the crosslink map by more than a predetermined number of records; calculating a difference value of a start position and an end position of the reference sequence information obtained from the crosslink map; determining a location of the target sequence in the genome sequence by a location shift corresponding to the difference value; and outputting the location of the target sequence in the genome sequence to a user, wherein a record for a sequence information recorded in the crosslink map comprises a name of a genome sequence, a version of the genome sequence, an identifier for a sequence information in the genome sequence, a start position and an end position of the sequence information in the genome sequence, and a length of the sequence information in the genome sequence..

The Supreme Court has enunciated a definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself. A claimed process is patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. See *Benson*, 409 U.S. at 70 ; *Diehr*, 450 U.S. at 192 ; see also *Flook*, 437 U.S. at 589 n.9 ; *Cochrane v. Deener*, 94 U.S. 780, 788 (1876). The same test is

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emphasized by the court in *In re Bilski* as the only test for determining whether a claimed method is a statutory process. *Id.*

In the instant case, the claimed process is not tied to any particular machine or apparatus. Moreover, there is no physical transformation because the claims are drawn to a process of merely manipulating nucleic acid sequence data without transforming an article or physical subject to a different state or thing. Therefore, at least one embodiment of the claimed method is not a statutory process.

Amendment of the claims to be tied to a particular machine or achieve a physical transformation may overcome the rejection.

However, applicant is reminded that the court has pointed out that the involvement of the particular machine/apparatus or transformation in a claimed process must not merely be insignificant extra-solution activity. See *Flook*, 437 U.S. at 590. A machine only recited in the data gathering step or an outputting step or preamble would fall into this category of insignificant extra-solution activity.

With regard to claims 1-2, 4-6, 12, and 15, while the systems may appear to be tangible, they may not be a specific particular machine or apparatus. The various “units” and “portions” of the system are not clearly disclosed and claimed as tangible hardware components of the system and may be completely software driven. In *Benson*, the limitations tying the process to a computer were not actually limiting because the fundamental principle at issue, a particular algorithm, had no utility other than operating on a digital computer. *Benson*, 409 U.S. at 71-72.

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Thus, the claim's tie to a digital computer did not reduce the pre-emptive footprint of the claim since all uses of the algorithm were still covered by the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4-7, 9-12, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benson et al. (Nucleic Acids Research, 1999, Vol. 27, pages 38-43; 2002, Vol. 30, pages 17-20) in view of Wheeler et al. (Nucleic Acids Research, 2002, Vol. 30, pages 13-16).

The claims are drawn to a method and system for determining the location of a target sequence in a genome.

Benson et al. disclose the system of database GenBank and methods of searching the database with a query.

Benson et al. disclose that the GenBank system comprises a plurality of records of different types of sequences including cDNA and genome sequences of different organisms and including different versions of sequences. The database includes different divisions and each division includes different files. For each record, it includes sequences identifiers and accession numbers, scientific name, taxonomy of the source organism, and a table that lists length of the sequence, etc. and features that identifiers coding regions and other sites of biological significance, such as transcription units, intron/exon boundaries, sites of mutations or modifications and other sequence features. See at least page 39, left column. These tables are interpreted as a crosslink map because they link the various sequence features such as intron/exon boundaries and transcriptional units with the locations in the sequences. Benson et al. also disclose various methods of searching the databases including BLAST and PowerBLAST. In the BLAST method, when a query sequence is provided, which is interpreted as being the target sequence recited in the instant claims, the BLAST system searches the entire database of records to find homologous sequences and locations of the query sequence (target sequences) in the sequences including genome sequences in the database, and displays the location of the query/target sequence in the various database record sequences in the form of alignments.

Benson et al. maintains an annual update in the journal of Nucleic Acids Research, and the update in 2002 is provided herein. In the 2002 update, Benson et al. once again stressed the usefulness of BLAST in the sequence similarity searching and pointed out that "BLAST is discussed in more detail in a separate article in this issue," which is provided herein as a supporting reference.

While Benson et al. do not explicitly recite a system comprising a storage unit, an information search unit and a location estimation unit, as recited in the instant claims, given that all the functions performed by these units in the claims are also performed in Benson et al., it would have been readily apparent to one having ordinary skill in the art that the system of BLAST+GenBank includes all these units. Furthermore, a computer program or algorithm for performing all these functions must have to be stored in a computer readable medium in the system disclosed by Benson et al. in order to perform the sequence searching by a computer, etc. as BLAST searches would have been extremely well known and widely used since its publication in 1990.

Applicant's arguments filed 8/13/08 have been fully considered but they are not persuasive. Applicant argues that Benson et al. are silent with respect to at least a crosslink map as in claim 7 that comprises records of sequence information for a plurality of versions of a genome sequence. This is not found persuasive. As set forth in the previous Office action and reiterated above, Benson et al. disclose that the GenBank system comprises a plurality of records of different types of sequences including cDNA and genome sequences of different organisms including different versions of sequences. The database includes different divisions and each division includes different files. For each record, it includes sequences identifiers and accession numbers, scientific name, taxonomy of the source organism, and a table that lists length of the sequence, etc. and features that identifiers coding regions and other sites of biological significance, such as transcription units, intron/exon boundaries, sites of mutations or modifications and other sequence features. See at least page 39, left column. These tables are interpreted as a crosslink map because they link the various sequence features such as

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intron/exon boundaries and transcriptional units with the locations in the sequences. Applicant argues that the table of features taught by Benson et al. is for a single sequence entry not comprising records of sequence information for a plurality of versions of a genome sequence. This is unpersuasive because as stated above, it is all these tables not a particular table that are interpreted to be the crosslink map. Applicant further argues that Benson et al. do not teach determining a reference group comprising a reference sequence for an organism, calculating a difference value of a start position and an end position of the reference sequence or determining a location of the target sequence in the genome sequence by a location shift. This is not found persuasive because as would have been recognized by one of ordinary skill in the art, when the BLAST software searches the database for a query sequence, which can be interpreted as a reference, it compares all the sequences including the start and end position of the query sequence with all sequences in the database and determines the location of the query sequence in the sequence(s) identified by the software to be homologous with, and if the identified sequences are genomic sequences such as human genome sequences which are in GenBank, it determines the location of the query sequence in the genome sequences.

In the arguments filed 5/12/09, applicant argues that Benson et al. are silent with respect to the location estimation unit for determining a reference group comprising a reference sequence information for an organism having the limitations recited in claim 1, etc. See page 3 of 5 of the response. This is not found persuasive. As set forth in the previous Office action and reiterated above, it would have been recognized by one of ordinary skill in the art that when the BLAST software searches databases such as GenBank, for a query sequence, which can be interpreted as a reference, it compares all the sequences including the start and end position of

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the query sequence with all sequences in the database and determines the location of the query sequence in the sequence(s) identified by the software to be homologous with, and if the identified sequences are genomic sequences such as human genome sequences which are in GenBank, it determines the location of the query sequence in the genome sequences.

Furthermore, as referenced by Benson et al. (2002), Wheeler et al. disclose BLAST and many more other search tools such as the OriFinder, etc. With regard to NCBI BLAST, Wheeler et al. disclose that the BLAST outputs an alignment format called the "HitTable," which provides a compact, tabular summary of the BLAST search results including, for each database hit, the positions of alignment starts and stops, couple with scores and Expectation Values. Wheeler et al. continue to disclose that in addition, BLAST can generate a taxonomically organized output that shows the distribution of BLAST hits by organism in three formats. See at least page 14, left column.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Shubo (Joe) Zhou/

Shubo (Joe) Zhou, Ph.D.

Primary Examiner